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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,179	03/27/2001	Ryo Nakashige	033808/027 8739	3835
38327	7590	09/23/2004	EXAMINER	
REED SMITH LLP 3110 FAIRVIEW PARK DRIVE, SUITE 1400 FALLS CHURCH, VA 22042			MARSCHER, ARDIN H	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/819,179

**Applicant(s)**

NAKASHIGE ET AL.

**Examiner**

Ardin Marschel

**Art Unit**

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-8 and 14-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-8 and 14-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ( <u>1 sheet</u> ). | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on 6/29/04, has been entered.

Applicants' arguments, filed 6/29/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### **VAGUENESS AND INDEFINITENESS**

Claims 3-8 and 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3, lines 3 and 5, the limitations "first" and "second" are respectively set forth but without indicating what is meant regarding these limitations as to antecedent basis. In lines 2 and 4, "a first ratio" and "a second ratio", respectively, are set forth but the wording of lines 3 and 5 do not clearly point to said ratios as being what is meant by the noted limitations in lines 3 and 5. Alternatively, "first" and "second" in lines 3 and 5 may indicate first and second experiments or possibly first and second time points for

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gene expression. Clarification via clearer claim wording is requested. Claims which depend directly or indirectly from claim 3 also are rejected hereinunder due to their dependence.

Claims 15 and 17 are vague and indefinite due to depending from a canceled claim thus resulting in unclarity as to what limitations are actually meant to be present in claims 15 and 17. Clarification via clearer claim wording is requested.

In claim 3 samples A, B, and C are cited but confusingly the dataset expressed as "(b/a, c/A, 1)" lacks clear antecedent basis as to what is meant for "b", "c", and "A". It may be assumed that "b" is an expression level for a gene in sample B etc. but this is an assumption and not clearly stated as such in claim 3. Also, the mixing of non-capitalization of "b" and "c" vs. "A" may be interpreted as indicating differing parameters within samples B and C vs. A but this is not clearly and concisely explained in the claim. Clarification via clearer claim wording is requested. Claims which depend directly or indirectly from claim 3 also are rejected hereinunder due to their dependence.

The gene expression levels of Samples A, B, and C apparently include a plurality of gene expression levels for each Sample. Therefore, what is meant by "r" in lines 8-9 of claim 3 is vague and indefinite because it is stated as being calculated for a dataset which corresponds to said plurality of genes yet confusingly there is no summation over said plurality of genes or other calculational directive in the claim by which to calculate such a parameter for a complex plural gene dataset thus making it vague and indefinite as to what "r" is meant to be for the dataset. Clarification via clearer claim wording is requested. Claims which depend directly or indirectly from claim 3 also are rejected

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hereinunder due to their dependence. Similarly, claim 4 cites a R calculation without defining what calculation corresponds to the plurality of genes in the dataset.

### INFORMATION DISCLOSURE STATEMENT

Enclosed is a PTO 1449 with on citation thereon lined through due to lacking a date of publication as required. A search report is not a published document and therefore its date is not a date of publication.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 18, 2004

*Ardin H. Marschel* 9/18/04  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER